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FAY SHARPE LLP 1228 Euclid Avenue, 5th Floor The Halle Building Cleveland, OH 44115			EXAMINER TANNER, JOCELYN C	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/549,355

Applicant(s)

CARO ET AL.

Examiner

JOCELIN C. TANNER

Art Unit

3731

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 December 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 3-6, 9, 10, 12, 13, 15-24, 28, 30-33 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-940)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 12/10/10
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

This Office Action is in response to the Amendment filed 20 December 2010. Claims 3-6, 9, 10, 12, 13, 15-24, 28, 30-33 are currently pending. The Examiner acknowledges the amendments to claims 12 and 24, new claims 30-33

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 3-6, 9, 10, 12, 13 and 15-23 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. With respect to claim 12, the recitation "wherein the helical center line of the flow lumen and the helical portion have substantially equal pitches when the stent is expanded" appears to be new matter. The Applicant referenced figures 1 and 2 and page 6, lines 32-34 of the specification as having support for the equal pitches of the helical center line and helical portion. However, the specification discloses that the pitch of the helical center line may be varied by varying the pitch of the helical portion but fails to disclose that the helical portion has the same pitch as the helical center line. Furthermore, it is unclear if the drawings show the helical center line and helical portion as having the same pitch. In the event that the Applicant disagrees with the 35 U.S.C. 112, first paragraph rejection, please clarify and point out within the specification and the figures where the support is found for these limitations.

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 3-6, 9, 10, 12, 13, 15-24, 28, 30-33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

5. Regarding claim 12, since the transitional phrase does not appear within the claim until line 9, it is unclear if the limitations before the transitional phrase are being positively recited. Transitional phrases assist in defining the scope of a claim with respect to what unrecited additional components are excluded from the claim. For the purposes of art rejections, the positively claimed limitations occur following the transitional phrase in line 9.

6. Regarding claim 24, since the transitional phrase does not appear within the claim it is unclear what limitations are being positively recited or required for the claim. For the purposes of art rejections, the Examiner will interpret the claims as a stent.

7. Regarding claim 30, since the transitional phrase does not appear within the claim it is unclear what limitations are being positively recited or the scope of the claim. For the purposes of art rejections, the Examiner will interpret the claims as a stent.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

1. Claims 3-6, 12, 13, 15-19 and 21-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Houston et al. (US PGPub No. 2002/0179166A1) in view of Evans et al. (US Patent No. 5,709,713) and in view of Edwin et al. (US Patent No. 6,053,943).

2. Regarding claims **5, 6 and 12**, as best understood, Houston et al. discloses a conduit that may be a mesh stent (11) [0025] that appears to be expandable since it is disclosed as being collapsible [0021], however, is not expressly disclosed as being expandable, the stent having an expanded configuration that is substantially free of ribs and having a helical center line and a helix angle of 8° that is within the claimed range of less than or equal to 65° ([0010], [0022], [0050], [0051], Fig. 5). Houston et al. fails to disclose an amplitude having a value less than or equal to 0.7 of the internal diameter of the tubing and to expressly disclose a stent that is expandable from a collapsed configuration and outer wall portions including helical portions having more of a resistance to extension than adjacent portions of the stent.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have provided tubing having a helical center line with a claimed value of an amplitude less than or equal to 0.7 of the internal diameter, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. In re Boesch, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

Evans et al. teaches a mesh stent having a radially compressed and expanded configuration obtained by self-expansion or a force to the body to cause radial expansion that would include balloon expandable means (column 5, lines 53-60).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided the mesh stent of Houston et al. with expansion and collapsing means, as taught by Evans et al., to release and remove the stent during and following the desired treatment.

3. Edwin et al. teaches a graft (10) including a support structure or "helical portion"(26) wherein longitudinal strips are helically wrapped around the exterior of the graft such that when longitudinal and radial expansion occurs the amount of expansion is controlled by the amount of resistance applied upon the graft by the helical portion, thereby causing the portions contacting the helical portions to resist a degree of expansion, wherein upon expansion selectively hardened or weakened regions of the helical portions permit different expansion characteristics such that helical portions and the portions contacting the graft will have a degree of resistance to expansion as opposed to the adjacent graft regions (column 2, lines 48-65, column 4, lines 10-25, column 8, lines 1-10, 30-60, Fig. 1).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided a helical portion to the stent of the combination of Houston et al. and Evans et al., as taught by Edwin et al., to control the longitudinal and radial expansion ratios of the final structurally supported graft (column 4, lines 55-58).

4. Regarding claim 3, Edwin et al. teach strain relief sections or "helical portions" that may be co-extruded with the graft member such that the helical portions have an

increased amount of stent forming material relative to the amount of stent forming material of adjacent portions (column 10, lines 10-20).

5. Regarding claim 4, Edwin et al. teaches curved or "bent" portions of the helical portions wherein the bent portions remain bent when expanded (Fig. 1).
6. Regarding claim 13, Houston et al. discloses a helical center line formed by internal ridging that has an amplitude and tubing with an internal diameter. Houston et al. fails to disclose the value of 0.05 calculated by dividing the amplitude of the helical centre line by the internal diameter of the tubing.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have provided tubing with the claimed values found by dividing the amplitude of the helical centre line by the internal diameter, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

7. Regarding claim 15, Houston et al. discloses Houston et al. discloses a stent (300) having an expanded configuration with a helical center line and a helix angle of 8° that is within the claimed range of less than or equal to 15° ([0010]).
8. Regarding claim 16, Houston et al. discloses a stent having a circular cross-section (Fig. 5).
9. Regarding claim 17, Houston et al. discloses a helical center line of the stent extending over part of the overall length of the stent (Fig. 5).

10. Regarding claim **18**, Houston et al. discloses a helical center line of the stent extending over substantially the entire length of the stent (Fig. 5).
11. Regarding claim **19**, Houston et al. discloses a helical center line following a substantially helical path about a curved axis (Fig. 5).
12. Regarding claim **21**, Houston et al. discloses a helical centre line formed by internal ridging that has an amplitude and tubing with an internal diameter. Houston fails to disclose the value of 0.1 calculated by dividing the amplitude of the helical centre line by the internal diameter of the tubing.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have provided tubing with the claimed values found by dividing the amplitude of the helical centre line by the internal diameter, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

13. Regarding claim **22**, Houston et al. discloses a stent (11) undergoing a turn of the helix wherein the stent has a helical configuration with at least one helical turn (Fig. 5).
14. Regarding claim **23**, Houston et al. discloses a stent having a helical portion that has the same number of turns in the expanded and collapsed conditions (Fig. 5).
15. **Claims 9 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Houston et al. (US PGPub No. 2002/0179166A1) in view of Evans et al. (US Patent No. 5,709,713) in view of Edwin et al. (US Patent No. 6,053,943), as applied**

to claim 12 above, and further in view of Inderbitzen et al. (US Patent No. 5,484,411).

16. Regarding claim 9, the combination of Houston et al., Evans et al. and Edwin et al. discloses a balloon expandable stent (column 3, lines 2-6, Evans et al.). However, the combination of Houston et al. and Evans et al. fails to disclose a balloon having an expandable wall that resists extension more helical portions of the balloon.

Inderbitzen et al. teaches an expandable balloon used in angioplasty procedures including a longitudinally extending spiral wall (38) extending from the distal to proximal end of the balloon, formed integrally with the exterior surface of the balloon and radially restricting the expansion of the balloon along the longitudinally extending spiral path (column 3, lines 45-53, Fig. 2).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have constructed the balloon of the combination of Houston et al., Evans et al. and Edwin et al., with a helical portion, as taught by Inderbitzen et al., to exhibit a low crossing profile and to avoid the need to rotate the balloon within a vessel to ensure dilation.

17. Regarding claim 10, Inderbitzen et al. teaches a balloon having an exterior surface or expandable wall wherein the wall thickness is greater in sections include a spiral wall or "helical portion" (38) (Fig. 2).

18. Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Houston et al. (US PGPub No. 2002/0179166A1) in view of Evans et al. (US Patent

No. 5,709,713) in view of Edwin et al. (US Patent No. 6,053,943), as applied to claim 12 above, and further in view of Igaki et al. (US Patent No. 5,733,327).

Regarding claim 20, the combination of Houston et al., Evans et al. and Edwin et al. discloses all of the limitations previously discussed except for a pharmaceutical coating.

Igaki et al teach coating a stent to provide locally limited and long-term dosage of drugs (column 2, line 51 and column 3, lines 19-22).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided the stent of the combination of Houston et al., Evans et al. and Edwin et al., with the coating or drug induced fiber, as taught by Igaki et al., to provide locally limited and long-term dosage of drugs.

19. Claims 24 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Houston et al. (US PGPub No. 2002/0179166A1) in view of Evans et al. (US Patent No. 5,709,713) in view of Cymbalisky (US Patent No. 6,896,007).

20. Regarding claim 24, as best understood, Houston et al. discloses a conduit that may be a mesh stent (11) [0025] that appears to be expandable since it is disclosed as being collapsible [0021], however, is not expressly disclosed as being expandable, the stent having an expanded configuration that is substantially free of ribs and having a helical center line and a helix angle of 8° that is within the claimed range of less than or equal to 65° ([0010], [0022], [0050], [0051], Fig. 5). Houston et al. fails to disclose an amplitude having a value less than or equal to 0.7 of the internal diameter of the tubing and to expressly disclose a stent that is expandable from a collapsed configuration.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have provided tubing having a helical center line with a claimed value of an amplitude less than or equal to 0.7 of the internal diameter, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. In *re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

Evans et al. teaches a mesh stent having a radially compressed and expanded configuration (column 5, lines 53-55).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided the mesh stent of Houston et al. with expansion and collapsing means, as taught by Evans et al., to release and remove the stent during and following the desired treatment.

However, the combination of Houston et al. and Evans et al. fails to disclose a conduit having a helical center line having a helix angle and/or amplitude that varies along the length of the stent.

Cymbalisky teaches a conduit having a helical center line (Fig. 5) wherein the helix angle and/or amplitude of the center line varies or changes form from one axis to another along the length of the stent, the helical center line having the capability of introducing a gentle swirl to increase the swirling of the fluid (column 3, lines 28-46).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided the mesh stent of the combination of Houston et al. and Evans et al., with a varying helix angle or amplitude, as taught by Cymbalisky, to provide directional flow changes (column 3, lines 12-15).

21. Regarding claim **28**, Cymbalisty teaches having a pitch and amplitude that change along the length of the tubular member and it would have been obvious to apply this to the stent of Houston as discussed above (column 3, lines 28-46).

22. **Claims 30-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Houston et al. (US PGPub No. 2002/0179166A1).**

23. Regarding claims **30-33**, as best understood, Houston et al. discloses a stent including an outer wall formed of a mesh structure or a "plurality of strands" that is capable of being collapsed and expanded, is capable of following a substantially helical center line (fig. 5). Houston et al. also discloses a mesh structure (400) wherein a helical portion (13a) formed of wires or "strands" (13a) is interspersed or integral with the support wires (14a, b). Therefore, it would have been obvious to have provided a integral helical portion to the outer wall that provides flow guidance to the stent.

Response to Arguments

9. Applicant's arguments filed 20 December 2010 have been fully considered but they are not persuasive. In response to applicant's argument that Cymbalisty is nonanalogous art, it has been held that a prior art reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the applicant was concerned, in order to be relied upon as a basis for rejection of the claimed invention. See *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). In this case, Cymbalisty teaches a tubular structure having undulations that may include a variety of serpentine paths with different pitches such that the suspension of solids is constant and the deposition of solids along the base of the

structure is prevented. The instant invention is directed toward promoting swirl flow and providing uniform velocity profile of the flow. Cymbalistry and the Applicant are working to reduce stagnant zones or build up of the flow within the stent would decrease the velocity and disturb the uniformity of the flow. With respect to claim 12, the Examiner respectfully states that the claims were being interpreted too narrowly. After thoroughly looking at the claims, the Examiner is unclear what is being positively recited as structure. Claim 12 includes a preamble but the transitional phrase does not occur until line 9, thus the Examiner is unclear what is being positively recited within the claim. Transitional phrases assist in defining the scope of a claim with respect to what unrecited additional components are excluded from the claim. Since the Examiner cannot read the specification into the claim, the positively recited structure must be clearly defined within the claim. Claim 12 currently requires the outer wall of a stent to have a helical portion which in the expanded condition extends longitudinally and circumferentially and which upon expansion of the stent the helical portion resists extension. Regarding claims 24 and 30, the Examiner respectfully points out that the claims do not contain a transitional phrase. Since there is no transitional phrase, it can only be assumed that the entire claim is the preamble. Therefore, it is unclear what is being positively recited within the claim.

Conclusion

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JOCELIN C. TANNER whose telephone number is (571)270-5202. The examiner can normally be reached on Monday through Thursday between 9am and 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anh Tuan Nguyen can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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